#### (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

# (19) World Intellectual Property Organization

International Bureau





(43) International Publication Date 10 June 2004 (10.06.2004)

**PCT** 

## (10) International Publication Number WO 2004/047734 A3

- (51) International Patent Classification<sup>7</sup>: A61K 48/00, 31/70, 31/715, A01N 43/04, C07H 21/04, 21/02
- (21) International Application Number:

PCT/US2003/037157

(22) International Filing Date:

21 November 2003 (21.11.2003)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data: 60/428,643

21 November 2002 (21.11.2002) US

- (71) Applicants (for all designated States except US): BAY-HILL THERAPEUTICS, INC. [US/US]; 3430 West Bayshore Road, Suite 201, Palo Alto, CA 94303 (US). THE BOARD OF TRUSTEES OF THE LELAND STANFORD UNIVERSITY [US/US]; Office of Technology Licensing, 1705 El Camino Real, Palo Alto, CA 94306-1106 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): GARREN, Hideki [US/US]; 417 E. Meadow Drive, Palo Alto, CA 94306 (US). HO, Peggy P., [US/US]; 11119 Flowering Pear Drive, Cupertino, CA 95014 (US). STEINMAN, Lawrence [US/US]; 1020 Vernier Place, Stanford, CA 94305 (US).
- (74) Agents: SHERBINA, Nicholas V., et al.; TOWNSEND and TOWNSEND and CREW LLP, Two Embarcadero Center, 8th Flr., San Francisco, CA 94111 (US).

- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

#### **Declaration under Rule 4.17:**

of inventorship (Rule 4.17(iv)) for US only

#### **Published:**

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (88) Date of publication of the international search report: 12 August 2004

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHODS AND IMMUNE MODULATORY NUCLEIC ACID COMPOSITIONS FOR PREVENTING AND TREATING DISEASE

(57) Abstract: This invention relates to methods and compositions for treating or preventing disease comprising the administration of immune modulatory nucleic acids having one or more immune modulatory sequences (IMSs). The invention further relates to the means and methods for the identification of the IMSs for preventing or treating disease, more particularly the treatment and prevention of autoimmune or inflammatory diseases. The invention also relates to the treatment or prevention of disease comprising the administration of the immune modulatory nucleic acids alone or in combination with a polynucleotide encoding self-protein(s), -polypeptide(s) or -peptide(s) or -peptide(s). The present invention also relates to methods and compositions for treating diseases in a subject associated with one or more self-protein(s), -polypeptide(s) or -peptide(s) that are present in the subject and involved in a non-physiological state.



## " INTERNATIONAL SEARCH RÉPORT

International application No.

PCT/US03/37157

		101/0303/3/13/	· ·
A. CLAS IPC(7) US CL	SIFICATION OF SUBJECT MATTER  : A61K 48/00, 31/70, 31/715; A01N 43/04; C0  : 536/23.1, 24.1; 514/44, 54	7H 21/04, 21/02	
According to	International Patent Classification (IPC) or to both n	ational classification and IPC	
B. FIEL	DS SEARCHED		
	cumentation searched (classification system followed 36/23.1, 24.1; 514/44, 54	by classification symbols)	
Documentation	on searched other than minimum documentation to the	e extent that such documents are include	d in the fields searched
	ta base consulted during the international search (nan ontinuation Sheet	ne of data base and, where practicable, s	earch terms used)
	JMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where ap		Relevant to claim No.
X/P	ZEUNER et al. Reduction of CpG-induced arthritis oligodeoxymucleotides. Arthritis and Rheumatism. 2219-2224, see entire document.		7-10
<b>X/P</b>	HO et al. An immunomodulatory GpG oligonucleor via the innate and adaptive immune systems. J. Imm 4926, see entire document.		1-6, 11-24
x	STACEY et al. Immunostimulatory DNA as an adj Leishmania major. Ifection and Immunity. August 3726, see entire document.	uvant in vaccination against 1999, Vol. 67, No. 8, pages 3719-	7-10
x	US 6,225,292 B1 (RAZ et al) 01 May 2001 (01.05.	2001), see entire document.	7-10
x	US 6,194,388 B1 (KRIEG et al) 27 February 2001	(27.02.2001), see entire document.	1-24
x	US 2002/0164341 A1 (DAVIS et al) 07 November document.	2002 (07.11.2002) see entire	1-24
Further	documents are listed in the continuation of Box C.	See patent family annex.	
"A" document	pecial categories of cited documents; defining the general state of the art which is not considered to be lar relevance	"T" later document published after the int date and not in conflict with the appli principle or theory underlying the inv	cation but cited to understand the
•	plication or patent published on or after the international filing date	"X" document of particular relevance; the considered novel or cannot be conside when the document is taken alone	
	which may throw doubts on priority claim(s) or which is cited to the publication date of another citation or other special reason (as	"Y" document of particular relevance; the considered to involve an inventive ste combined with one or more other suc	p when the document is
"O" document	referring to an oral disclosure, use, exhibition or other means	being obvious to a person skilled in the	
	published prior to the international filing date but later than the late claimed	"&" document member of the same patent	family
	ctual completion of the international search	Date of mailing of the international set	arch report
	4 (27.04.2004)	Authorized officer	
Mail Stop DCT Atta: ISA/IIS			1 / 1/1
Cor P.C	nmissioner for Patents  D. Box 1450	Nita M. Minnifield	V William
	xandria, Virginia 22313-1450 o. (703) 305-3230	Telephone No. 703-308-0196	- 0.1
	A/210 (second sheet) (July 1998)	<u> </u>	

	/US		

### INTERNATIONAL SEARCH REPORT

US 2003/0181406 A1 (SCHETTER et al) 25 September 2003 (25.09.2003), see entire document.	1-24
·	

	PCT/US03/37157
INTERNATIONAL SEARCH REPORT	·
t t	
'	
	•
Continue to an appropriate to the posterior of the continue to	
Continuation of B. FIELDS SEARCHED Item 3:	WINDO LADIO AIDI WEST
EMBASE, BIOSIS, USPATFULL. PGPUB, MEDLINE, CABA, AGRICOLA,	WPIDS, JAPIO, NPL, WEST
Secret to-me, inventor names heaterial day microbial and and motif autoima	mana disease treatment iddm erthritis nolyG region
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimn	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	nune disease, treatment, iddm, arthritis, polyG region,
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	
Search terms: inventor names, bacterial dna, microbial cpg, gpg motif, autoimm multiple sclerosis	